

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim 25 is requested to be cancelled.

Claim 1 is currently being amended to incorporate the limitations of claim 25. Accordingly, the amendment to claim 1 adds no new matter.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1, 14, 17-22, and 33-34 are under examination. Claims 1, 14-23, and 26-34 are pending. Claims 2-13 and 24-25 have been canceled. Claims 15-16, 23 and 26-32 have been withdrawn as non-elected.

I. REJECTION UNDER 35 U.S.C. §112 (NEW MATTER)

The claims stand rejected as non-compliant with the written description requirement of Section 112, first paragraph. Office Action, page 2.

The Office asserted that the limitation “wherein the composition is solid or pasty at room temperature” in claim 1 is not supported by the description.

Applicant has obviated this rejection by amendment. To further prosecution, the term “wherein the composition is solid or pasty at room temperature” has been cancelled from claim 1.

For the record, however, Applicant traverses and respectfully points out that the specification provides explicit support for the limitation “wherein the composition is solid or pasty at room temperature” in claim 1. The specification states “[t]he composition according to the invention is advantageously presented in a form which is solid or pasty at room temperature” (specification, page 3, lines 34-36).

II. REJECTION UNDER 35 U.S.C. §102(B) (NOVELTY)

Claims 1, 14, 17, 19, and 33-34 stand rejected as anticipated by U.S. 4,999,207 (“Buckholz”).

Applicant has obviated this rejection by amendment. Claim 1 has been amended to incorporate the limitations of claim 25, i.e., “wherein the composition is in the form of soft or hard capsules”.

Claim 25 was not subject of the anticipation rejection. Accordingly, this ground of rejection should be withdrawn.

For the record, Applicant disagrees with this ground of rejection against claim 1 prior to the present amendment.

Buckholtz discloses the use of sclareolide in augmenting or enhancing the organoleptic properties of foodstuffs. Example XX of Buckholtz discloses the composition of a ground sausage, containing (among others) beef suet (6,8%), different vegetal oils (30%) and oleoresin capsicum (21%). As suet beef is considered to be a lipophilic additive which is solid or pasty at room temperature, the Office states that the composition disclosed by Buckholtz is the same as the present invention.

As a matter of fact, the composition of the invention stimulates thermogenesis, which is not the case of ground sausage. Applicant notes that the preamble limits claim 1 by clear definition (“A composition which stimulates thermogenesis”) rather than by indicating an intended use (e.g., by stating “A composition for stimulating thermogenesis”).

In any event, the ground sausage of Buckholtz does not stimulate thermogenesis and is not in the form of soft or hard capsules.

Thus, the composition of the present invention is new in view of the one disclosed in Buckholtz, and this objection should be withdrawn.

Also, Applicant notes that the composition as disclosed in amended claim 1 is not disclosed in GB 2,367,493 (“McClymont”) that was previously cited. McClymont does not disclose or suggest capsules. Indeed, the rodent repulsive composition of McClymont is

under liquid form (page 4, lines 18-21) for advantageous dispersing on earth or trees to deter rodents, and is therefore not intended to be encapsulated at all.

III. REJECTION UNDER 35 USC §103(A) (OBFUSCITY)

The claims stand rejected as obvious over of the combination of US 5,273,754 (“Mann”), US 2002/0192308 (“Mamana”), and JP 2001064672 (“Hosoya”).

Applicant respectfully traverses. The rejection should be withdrawn for three reasons. First, unexpected results disclosed in the present specification would overcome any prima facie case made out by the cited references. Second, the references fail to establish a prima facie case of obviousness, because the combined references fail to satisfy the limitation “lipophilic additive which is solid or pasty at room temperature”. Third, the rejection is improperly based on hindsight in view of the present invention.

A. The invention provides unexpected results

The MPEP instructs examiners as follows:

Rebuttal evidence and arguments can be presented in the specification, *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995) ...

Office personnel should consider all rebuttal arguments and evidence presented by applicants. See, e.g., *Soni*, 54 F.3d at 750, 34 USPQ2d at 1687 (error not to consider evidence presented in the specification).

Surprisingly, Applicant has discovered that the incorporation of a formulation base containing both a vegetable and/or mineral oil and a lipophilic additive which is solid or pasty at room temperature results in a composition which lacks any irritant effect on the gastric mucosa (see the *in vivo* test on page 11).

The specification discloses the results of “Digestive Tolerance Tests on Healthy Subjects” demonstrating that the invention provides a surprising improvement in the reaction of human subjects to capsaicin (page 11, line 9, et seq.).

Accordingly, even if a prima facie case of obviousness were properly made out, which Applicant denies as explained below, such a prima facie case would be effectively rebutted by the unexpected results disclosed in the present specification.

B. The Rejection is based on impermissible hindsight

The Office has combined the three documents Mann, Mamana, and Hosoya by improper hindsight consideration of the invention.

Applicant respectfully observes that, even if a man skilled in the art had the idea to look in documents dealing with body weight control, the probability for him to choose the three quoted documents was very faint.

As a matter of fact, there are thousands of molecules known to have an effect on weight control. To illustrate this point, Applicant submits the review article of Pittler et al (*Am J Clin Nutr* 2004; 79: 529-36) and the botanical draft list of Article 13 Health Claims of the European Commission (both documents filed concurrently herewith in an Information Disclosure Statement), showing that, for natural botanical compounds only, more than 20 compounds were known for decades to influence body weight.

The Office has not indicated what would lead a person ordinarily skilled in the art who wants to realize a composition which stimulates thermogenesis so as to, potentially, control body weight, to chose specifically the three cited documents Mann, Mamana, and Hosoya.

Applicant faithfully considers that it was none: nothing in the cited documents triggers the man skilled in the art to combine these documents among others.

Mann teaches “an undesirable burning sensation sometimes results upon the ingestion of the heating carminative substance” (column 3, lines 31-33). However, Mann does not teach how to alleviate this burning sensation. Also, neither Mamana nor Hosoya, which disclose respectively an appetite suppressant composition and a weight reducing composition, teach how to counteract the gastric burning effect of the capsaicinoids.

As a matter of fact, there is no link between the three documents:

- Mann teaches an appetite suppressant composition leading to a decrease in weight, comprising at least i) a heating carminative substance, and ii) a cooling carminative substance. Mann does not refer to lipophilic additives or oils.

- Mamana discloses an appetite suppressant composition comprising green tea or green tea leaf extracts. Also, Mamana teaches a method of controlling weight by replacing at least one meal with soy based meal. Mamana is silent concerning capsaicinoids, or lipophilic additive or oils.
- Hosoya teaches a fat metabolizer ingested in very small amount comprising fats and oils, which is actually a mixture of specific proportions of mono-, di-, and tri-glycerides whose fatty acids moieties are obtained from vegetable (linseed, sesame and rapeseed) or fish oils. As these fatty acids are unsaturated, resulting mono-, di-, and tri-glycerides are liquid at room temperature, and are therefore not pasty or solid at room temperature. Thus, Hosoya does not disclose any lipophilic additive which is pasty or solid at room temperature. Moreover, Hosoya is silent concerning capsaicinoids.

Hence, the only way to choose these three references for combination was to choose them starting from the invention. Such reasoning is erroneously based on hindsight reconstruction of the invention.

Therefore, considering all the published prior art documents, a person of ordinary skill in the art would not have combined the three documents.

C. Combining Mann, Mamana, and Hosoya would not yield the present invention.

Even if Mann, Mamana, and Hosoya were combined, the result would not yield the present invention, because these documents fail to disclose or suggest the use of a “lipophilic additive which is solid or pasty at room temperature” as recited in claim 1.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” M.P.E.P. 2143.03, quoting *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Mann teaches an appetite suppressant composition leading to a decrease in weight, comprising at least i) a heating carminative substance, and ii) a cooling carminative substance. In a preferred embodiment, said heating carminative substance is capsaicin. Mann teaches that the heating carminative substance is “a substance having a gastric heating effect and exhibits a local anaesthetic effect in the stomach (particularly upon the gastric

nerves controlling hunger) (column 2, lines 30-33)". However, "an undesirable burning sensation sometimes results upon the ingestion of the heating carminative substance" (column 3, lines 31-33).

Thus, it was known that heating carminative substances such as capsaicin were efficient to decrease weight, but were also associated with pain and irritation in the gastric mucosa.

For a person of ordinary skill in the art seeking to realize an appetite suppressant composition containing capsaicinoids as active principle for regulating weight, the problem was to find a way to bypass these painful symptoms.

Mann does not teach to add any formulation base containing a vegetable oil and/or mineral oil and a "lipophilic additive which is solid or pasty at room temperature" as presently claimed. Instead, Mann only discloses adding either "cooling carminative substances" (e.g., peppermint, menthol, spearmint, carvone or mixture thereof), amino acids (e.g., L-methionine, D-phenylalanine, glycine or mixtures thereof), and/or anxiolytic substances (e.g., valerian, damiana, chamomile, kava, passion flower, hops, skullcap, St John's Wort, extracts thereof or mixtures thereof).

Moreover, neither Mamana nor Hosaya, which disclose respectively an appetite suppressant composition and a weight reducing composition, teach to counteract the gastric burning effect of the capsaicinoids by the use of formulation base containing a vegetable oil and/or mineral oil and a lipophilic additive.

None of these documents teach the use of a lipophilic additive which is solid or pasty at room temperature in their composition.

As a matter of fact, and contrary to what the Office alleged, Hosoya does not disclosed lipophilic additive which are solid or pasty at room temperature: monoglycerides, diglycerides and triglycerides isolated by transesterification from vegetable and fish oils are indeed liquid at room temperature, depending on their fusion temperature and length of saturated chain.

To stress this, Applicant submits the following table highlighting the fusion temperatures of such oils (data from EngineeringToolBox Website):

Oil	Melting Temperature (°C)
Castor Oil	-18
Coconut Oil	25
Cotton Seed Oil	-1
Linseed Oil	-24
Mutton Tallow	42
Olive Oil	-6
Palm Kernel Oil	24
Palm Oil	35
Peanut Oil	3
Rapeseed Oil	-10
Sunflower Oil	-17
Soybean Oil	-16
Tung Oil	-2.5

In contrast, in the present invention the exemplified glycerides are those whose fatty acid moiety consists of palmitic and stearic acid, which are saturated fatty acids, and therefore are pasty or solid at room temperature.

Applicant has here shown that:

- Mann, Mamana, and Hosoya fail to disclose lipophilic additives which are solid or pasty at room temperature, and
- Mann, Mamana, and Hosoya fail to disclose the advantageous anti-burning effects of lipophilic additive that are solid or pasty at room temperature.

It was thus not obvious for the man skilled in the art to associate a formulation base containing a lipophilic additive which is solid or pasty at room temperature with a capsaicinoid in order to attenuate the capsaicinoid's gastric burning effect.

Moreover, as none of these documents teach the use of lipophilic additive which is solid or pasty at room temperature in their composition, a person of ordinary skill in the art, who had by pure chance combined the teaching of Mann, Mamana, and Hosoya would not have realized the present invention.

For all the reasons provided above, the obviousness objection should be withdrawn.

D. All dependent claims are nonobvious

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Claim 1 is nonobvious for the reason presented above. The dependent claims under examination all depend, directly or indirectly, from claim 1. Accordingly, the dependent claims are also nonobvious.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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